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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------|------------------|
| 10/613,395 | 07/03/2003 | William M. Appling | ANGIO P-32/500622.20045 | 4468 |
| 7590 | 12/15/2005 | | EXAMINER FARAH, AHMED M | |
| Harry K. Ahn, Esq. Reed Smith LLP 599 Lexington Avenue New York, NY 10022 | | | ART UNIT | PAPER NUMBER |
| | | | 3735 | |
| DATE MAILED: 12/15/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/613,395 | Applicant(s) APPLING ET AL. | |
| | Examiner Ahmed M. Farah | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-12, 14-24, 26, 27 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-12, 14-24, 26, 27 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 8-12, 14-24 and 26 are again rejected under 35 U.S.C. 102(b) as being anticipated by Mueller U.S. Patent No. 5,725,521.

Mueller discloses a transmyocardial revascularization apparatus and methods of use, the apparatus comprising: a catheter device comprising at least one optical fiber **54** (see Figs. 3 and 4); a first tube, **58, 106**, surrounding the optical fiber, and second tube, **50,102**, surrounding the first tube (see Figs. 3, 5A, respectively); and a spacer **70** arranged near the distal end of the optical fiber and operable to position the distal end of said optical fiber away from the blood vessel as presently claimed (see Fig. 4).

As to claims 4, 5, 7, 10, 11, and 13-16, the spacer has a plurality of ribs, the ribs extending in a radial direction into a deployed state as claimed (see Fig. 6B).

As to claims 17 and 18, the spacer includes a balloon positioned near the distal end of the optical fiber (see Fig. 6A).

Independent claims 1, 8, 22 and 26 recite a spacer "directly attached to the optical fiber." The applicants further argue that the prior art fails to teach a spacer attached to the optical fiber as described in paragraph 43 of applicants' specification. However, contrary to the applicants' argument, paragraph 43 of the present application

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teaches that the spacer (ribs 19) is part of a sleeve 17 that is coaxially arranged around the optical fiber 3. This paragraph further teaches that sleeve 17 can be moved longitudinally relative to the optical fiber. This is a clear indication that the spacer is not physically attached to the optical fiber 3. therefore, the spacer 70 of Muller meets the claims as recited.

3. Claims 1-5, 8-12, 14-24 and 26 are again rejected under 35 U.S.C. 102(b) as being anticipated by Kittrell et al. U.S. Patent No. 5,693,043.

Kittrell et al disclose an endovascular laser treatment device and methods of use, the device comprising: a plurality of optical fibers **20**; a spacer **176** arranged near the distal end of the optical fibers; a first tube adapted to receive the optical fibers; and a second tube surrounding the first tube, the spacer being arranged near the distal portion of the second tube as presently claimed (see Figs. 11A, 18, and 24).

As to claims 17 and 18, the spacer includes a balloon positioned near the distal end of the optical fiber (see Fig. 18).

4. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Michaels EP 0 311 295 A2.

Michaels discloses an endovascular catheter device comprising: an outer sleeve **5**; an inflatable balloon **6**; an optical fiber **3**; and a spacer **4** attached to the distal end of the optical fiber (see Figures 1-3). Michaels further teaches that the spacer 4 is adapted to minimize the risk of damaging the artery wall (see col. 4, lines 30-48).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 27 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vascular Solution, Vari Lase™ (see Exhibit A) in view of DUETT™ Sealing Device (see Exhibit B).

Vascular Solution discloses alternative blood vessel sealing devices and methods of use, the sealing devices selected from the group consisting of Vari Lase™ and DUETT™.

In the case of the Vari Lase™, a catheter device is inserted into the blood vessel; and laser energy is applied to the blood vessel walls, through the distal end of an optical fiber, while longitudinally removing the catheter device from the blood vessel. However, this system fails to teach the use of a spacer at the distal end of the catheter/optical fiber as presently claimed.

The DUETT, which is an alternative system for sealing a blood vessel, comprises a catheter having an inflatable distal balloon, the balloon adapted to prevent damage to the blood vessel walls during treatment. Therefore, at the time of the applicant's invention, one skilled in the art would have modified Vari Lase™ in view of DUETT™ sealing device and use a distal balloon in order to minimize the risk of damaging the walls of the blood vessel as presently claimed.

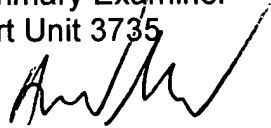
Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on (571) 272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ahmed M Farah
Primary Examiner
Art Unit 3735



December 11, 2005.